

AMENDMENTS TO THE CLAIMS

1. **(Currently Amended)** A process for administering one or more biologically active agents to an animal, comprising administering to said animal on a single occasion progressively increasing doses of said one or more biologically active agents which are released in a form that releases progressively increasing doses of said one or more biologically active agents over a predetermined period of time ~~from a delivery means which is administered to an animal on a single occasion.~~

2. **(Currently Amended)** A process as claimed in claim 1 wherein said one or more biologically active agents are selected from the group consisting list of: antibiotics, ~~anthelmintics~~ antihelminthics, peptides, proteins, carbohydrates, DNA, RNA, hormones, nutraceuticals, vitamins, trace-elements, ~~immunising-immunizing~~ agents ~~or~~ and any combination thereof.

3. **(Currently Amended)** A process as claimed in ~~either~~ claim 1 ~~of claim 2~~ wherein said one or more biologically active agents comprise an adjuvant and/or a pharmaceutically acceptable carrier.

4. **(Currently Amended)** A process as claimed in ~~any one of claims 1 to 3~~ claim 1 wherein the progressively increasing doses comprise sequentially doubling doses of said biologically active agents, ~~or sequentially increasing doses such as 25, 50, 75, 100 or 4, 8, 32, 150 active units.~~

5. **(Currently Amended)** A process as claimed in ~~any one of claims 1 to 4~~ claim 1 wherein the predetermined period of time at which said one or more ~~of~~ biologically active agents are administered is selected from the group consisting of: hours, days, weeks, ~~or~~ months and ~~or~~ any combination thereof.

6. **(Currently Amended)** A process as claimed in ~~any one of claims 1 to 5~~ claim 1 wherein said one or more biologically active agents is an ~~immunising-immunizing~~ agent and wherein said process comprises the administration to said animal of progressively increasing doses of one or more ~~immunising-immunizing~~ agents ~~which are released over a predetermined period of time from a delivery means which is administered to an animal on a single occasion.~~

7. **(Original)** A process as claimed in claim 6 wherein said one or more ~~immunising~~ immunizing agents comprise an antigen or combination of antigens.

8. **(Currently Amended)** A process as claimed in claim 6 ~~or claim 7~~ wherein said one or more ~~immunising-immunizing~~ agents comprise a vaccine or combination of vaccines.

9. **(Currently Amended)** A process as claimed in ~~any one of claims 6 to 8~~ claim 6 wherein said one or more ~~immunising-immunizing~~ agents are selected from the group consisting of: molecules that will induce protective immunity against a disease causing organism, ~~or~~ molecules that will induce functional immunity, and ~~or~~ any combination thereof.

10. **(Currently Amended)** A process as claimed in ~~any one of claims 6 to 9~~ claim 6 wherein the progressively increasing doses of said one or more ~~immunising-immunizing~~ agents are in the range of from about 0.1 µg to 1000 µg.

11. **(Canceled)**

12. **(Currently Amended)** A biologically active agent delivery composition comprising one or more biologically active agents whereby said composition ~~comprises means to enable~~ is configured to deliver progressively increasing doses of said one or more biologically active agents to be released over a predetermined period of time from a ~~delivery means which is administered to an animal on a single occasion~~ administration.

13. **(Currently Amended)** A biologically active agent delivery composition as claimed in claim 12 wherein said one or more biologically active agents are selected from the ~~list~~ group consisting of: antibiotics, ~~anthelmintics~~ antihelminthics, peptides, proteins, carbohydrates, DNA, RNA, hormones, nutraceuticals, vitamins, trace-elements, ~~immunising-immunizing~~ agents ~~or~~ and any combination thereof.

14. **(Currently Amended)** A biologically active agent delivery composition as claimed in ~~either claim 12 or claim 13~~ wherein said one or more biologically active agents comprise an adjuvant and/or a pharmaceutically acceptable carrier.

15. **(Currently Amended)** A biologically active agent delivery composition as claimed in ~~any one of claims 12 to 14~~ claim 12 wherein the progressively increasing doses comprise sequentially doubling doses of biologically active agents, ~~or sequentially increasing doses such as 25, 50, 75, 100 or 4, 8, 32, 150 active units.~~

16. **(Currently Amended)** A biologically active agent delivery composition as claimed in ~~any one of claims 12 to 15~~ claim 12 wherein the predetermined period of time at which said one or more of biologically active agents are administered is selected from the group consisting of: hours, days, weeks, ~~or~~ months ~~or~~ and any combination thereof.

17. **(Currently Amended)** A biologically active agent delivery composition as claimed in ~~any one of claims 12 to 16~~ claim 12 wherein said one or more biologically active

agents is an ~~immunising~~ immunizing agent and ~~wherein said delivery composition comprises means to enable~~ enables progressively increasing doses of one or more immunising agents to be released over a predetermined period of time from a delivery means which is administered to an animal on a single occasion.

18. **(Original)** A biologically active agent delivery composition as claimed in claim 17 wherein said one or more ~~immunising~~ immunizing agents comprise an antigen or combination of antigens.

19. **(Currently Amended)** A biologically active agent delivery composition as claimed in claim 17 ~~or claim 18~~ wherein said one or more ~~immunising~~ immunizing agents comprise a vaccine or combination of vaccines.

20. **(Currently Amended)** A biologically active agent delivery composition as claimed in ~~any one of claims 17 to 19~~ claim 17 wherein said one or more ~~immunising~~ immunizing agents are selected from the group consisting of: molecules that will induce protective immunity against a disease causing organism, ~~or~~ molecules that will induce functional immunity ~~or and~~ any combination thereof.

21. **(Currently Amended)** A biologically active agent delivery composition as claimed in ~~any one of claims 17 to 20~~ claim 17 wherein the progressively increasing doses of said one or more ~~immunising~~ immunizing agents are in the range of from about 0.1 µg to 1000 µg.

22. **(Currently Amended)** A biologically active agent delivery composition as claimed in ~~any one of claims 12 to 21~~ claim 12 wherein the delivery composition comprises two or more types of microspheres or microparticles, wherein each type of microsphere or microparticle ~~containing~~ contains a different dose of one or more biologically active agents and wherein said microspheres or microparticles comprise ~~comprising~~ biodegradable material which will degrade over a known time period so that the lowest dose of biologically active agents is released from a first type of microsphere or microparticle at a set time after administration, followed by the next highest dose of biologically active agents at the next predetermined time etc.

23. **(Currently Amended)** A biologically active agent delivery composition as claimed in ~~any one of claims 12 to 22~~ claim 12 wherein the delivery composition is located within a ~~delivery means comprising~~ a bioerodable device that releases progressively increasing amounts of the biologically active agents as it erodes.

24. **(Currently Amended)** A biologically active agent delivery composition as claimed in ~~any one of claims 12 to 23~~ claim 12 wherein the delivery composition is administered to an animal by way of injection, ingestion or implantation.

25. **(Original)** A biologically active agent delivery composition as claimed in claim 24 wherein the administration of the delivery composition takes place shortly after birth of an animal, or when maternally-derived antibody has decreased sufficiently for the young animal to be able to respond to the vaccination, and provides immunity without the need for further booster administration.

26. **(Currently Amended)** ~~A delivery means for use, a process as described in any one of claims 1 to 11 wherein the delivery composition is located within comprising a multicompartmental capsule containing~~ comprising a plurality of compartments with progressively increasing doses of one or more biologically active agents within the compartments, said ~~delivery means capsule~~ comprising an outer wall made of a at least one biodegradable substance which degrades over a pre-set period of time to release the smallest dose of biologically active agents, and one or more inner compartmental walls made of the same or different material that degrade over a longer period of time to release progressively increasing pulses of the biologically active agents

27. **(Currently Amended)** A ~~delivery means capsule~~ capsule as claimed in claim 26 wherein the biodegradable material of the outer wall is ~~be~~ selected from the group ~~comprising~~ consisting of: cholesterol/lecithin, polylactide, ~~and/or~~ polyglycolide copolymers, ~~one or more of a number of~~ cellulose polymers, polyacrylic acid, polymethylmethacrylate, cross-linked polyacrylic acid, polyeaprolactone, polyvinylpyrrolidine, polyvinylalcohol, polyethylene glycol, agarose, DEAE dextran microspheres, starch microspheres, ~~and/or~~ albumin microspheres, ~~or~~ gelatine gelatin microspheres, ~~or~~ and any combination thereof.

28. **(Currently Amended)** A ~~delivery means capsule~~ capsule as claimed in claim 26 ~~or claim 27~~ wherein the pre-set period of time within which the outer wall and inner compartmental walls degrade may be selected from the group consisting of: hours, days, weeks, ~~or~~ and months.

29-30 **(Cancelled)**

31. **(NEW)** The process of claim 4 wherein said sequentially increasing doses are 25, 50, 75, 100 or 4, 8, 32, 150 active units.

Int'l Appl. No. : PCT/NZ03/00115
Int'l Filing Date : June 5, 2003

32. (NEW) The process of claim 15 wherein said sequentially increasing doses are 25, 50, 75, 100 or 4, 8, 32, 150 active units.